J Clin Periodontol 2004; 31: 299–308 doi: 10.1111/j.1600-051X.2004.00527.x
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Journal of Clinical Periodontology

Submerged or non-submerged healing of endosseous implants to be used in the rehabilitation of partially dentate patients

A multicenter, randomized controlled clinical trial

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Cecchinato D, Olsson C, Lindhe J. Submerged or non-submerged healing of endosseous implants to be used in the rehabilitation of partially dentate patients. J Clin Periodontol 2004; 31: 299–308. doi: 10.1111/j.1600-051X.2004.00527.x

Acknowledgments

The participation of the following clinicians in the surgical and prosthetic treatment, as well as in the various clinical examinations of the patient sample included in this current study, is gratefully acknowledged: Franco Bengazi, Brescia; Giorgio Blasi, Genova; Daniele Boticelli, Rimini; Ian Cardarelli, Padova; Marco Giargia, Genova; Federico Gualini, Bergamo; Andrea Parpaiola, Padova and Antonio Rensi, Rimini.

Abstract

Objective: To evaluate bone-level alterations that occurred at implants of the Astra Tech® System that were placed in the load carrying, posterior parts of the dentition using either a submerged (two-stage) or a non-submerged (one-stage) installation protocol.

Material and Methods: Eighty-four patients that required 115 fixed partial dentures (FPDs or cases) entered the prospective study. All subjects were assigned one patient and $\geqslant$one case numbers. For the randomization of cases, a custom-made program based on balanced random permuted blocks was utilized. The cases were assigned to two treatment groups, namely one-stage installation procedure, non-submerged technique (group A) and two-stage installation procedure, submerged technique (group B). Several subjects contributed with cases to both groups A and B. Periodontal, endodontal and open caries lesions were treated prior to implant installation. All patients received careful oral hygiene instruction and training in self-performed plaque control measures.

The surgical technique used for fixture installation followed the outline described in the manual for the Astra Tech® System. The FPDs were placed 3 months (mandible) and 6 months (maxilla) following implant installation. Immediately following FPD placement, a baseline examination was performed that included assessment of *plaque*, *soft-tissue inflammation and bone level.* Clinicians who were otherwise not involved in the study performed the radiographic measurements. Clinical and radiographical examinations were repeated once a year after the baseline examination.

Data analysis: The primary outcome variable was the change in the bone level at the implants from the time of placement of the bridge (FPD) to the 1- and 2-year reexaminations. Fisher's permutation test was used to test if differences existed between groups A and B, and between patients (men/women, smokers/non-smokers, age), sites (maxilla/mandible) and implants (length, diameter). Pitman's test was used to study correlations between bone shape and quality data and different radiographic bone-level data.

Results: It was demonstrated that tissue healing following implant installation appeared to be independent of the surgical protocol, i.e. whether the marginal portions of the implants during surgery were fully or only partly submerged under the ridge mucosa. Thus, (i) in both treatment groups the number of implants that failed to osseointegrate (early failures) was small (<2%); (ii) at the end of the recommended periods of bone healing prior to loading, – in both groups, maxilla = 6 months and mandible = 3 months – the level of the marginal bone was close to the coronal rim of the fixture; group A: 1.54 ± 0.92 mm, group B: 1.31 ± 0.77 mm. The current study also demonstrated that irrespective of surgical protocol (two-stage, one-stage), implants supporting the FPDs exhibited only small amount of radiographic bone loss during the first year of function (group A: 0.02 ± 038 mm, group B: 0.17 ± 0.64 mm). Moreover, during the second year of function, the amount of additional bone loss that occurred in the two treatment groups was close to zero.
Conclusion: Periimplant bone-level change during function seemed to be unrelated to whether initial soft- and hard-tissue healing following implant installation had occurred under submerged or non-submerged conditions.

Key words: bone quality; gender; mandible; maxilla; non-submerged; periimplant bone loss; submerged

Accepted for publication 13 June 2003

Implants made of c.p. titanium are frequently used in the rehabilitation of totally and partially edentulous patients. Findings from several retrospective but also prospective clinical studies have documented that this kind of rehabilitation has not only a predictable short-term outcome but also a good long-term prognosis. It was further demonstrated that proper bone healing, i.e. ''osseointegration'' occurred at >90% of all of inserted implants and that the bone tissue at most implant sites remained unchanged with respect to both quality and quantity over time (for review see Cochran 1996, Esposito et al. 1998a, b).

A two-stage surgical technique was originally advocated in order to optimize the process of new bone formation and remodeling following implant installation (Brånemark et al. 1977). In the first stage, the implant was following the ostectomy procedure carefully inserted in the bone housing and submerged beneath the mucosa. After a healing period of about 3–6 months, the marginal part of the fixture was exposed and abutment connection performed. The predictable outcome of this two-stage installation technique was verified in several clinical trials that reported high success and survival rates for implants that were initially submerged (for review see Esposito et al. 1998a, b).

In subsequent studies, however, it was recognized that proper osseointegration and subsequent good long-term success could be obtained also with non-submerged implants, either one-piece implants (ITI® System; Straumann AG, Waldenburg, Switzerland) or two-piece implants (e.g. Brånemark® System; Nobel Biocare, Göteborg, Sweden, 3I® System; Implant Innovations, Wets Palm Beach, FL, USA) that were installed in a one-stage procedure (e.g. Ericsson et al. 1996, 1997, Collaert & De Bruyn 1998, Cochran 2000).

Abrahamsson et al. (1996) in a beagle dog experiment studied the marginal periimplant tissues at one non-submerged (ITI® – solid screw) and two submerged implant systems (Brånemark® System; Astra Tech® Implant System, Astra Tech, Mölndal, Sweden). The authors reported that the degree of ''bone-to-implant contact'' as well as the dimension of various components in the periimplant mucosa following healing was similar around all three implant systems studied. In a second dog study, Abrahamsson et al. (1999) compared the mucosa and the bone tissue surrounding implants of the Astra Tech® System that had been installed either in a one- (non-submerged) or a two-stage (submerged) surgical procedure. It was observed that parameters such as the length of the barrier epithelium of the periimplant mucosa, the height of the zone of connective tissue integration, the level of the marginal bone and the density of bone between threads were almost identical in the two experimental groups at the end of the healing period.

In various review articles (e.g. van Steenberge et al. 1999, Berglundh et al. 2002) it was concluded that implant failures were more frequent (i) in the maxilla than in the mandible and (ii) in the posterior segments of the dentition than in the anterior parts. It was suggested that the reason(s) for these differences in treatment outcome was related to the quality of bone tissue in various regions of the alveolar processes and to the amount and direction of load that was distributed to the implants during function.

The objective of the current prospective study was to evaluate bone-level alterations that occurred at implants of the Astra Tech® System that were placed in the load-carrying, posterior parts of the dentition using either a submerged (two-stage) or a non-submerged (one-stage) installation protocol.

Material and Methods

A parallel group, randomized, multicenter and controlled study was designed to determine if a difference existed between the outcome of treatment when implants of the Astra Tech® System were installed according to a one- or a two-stage protocol. The investigation was performed at one university clinic in Sweden and five affiliated clinical research centers (private offices) in Italy. In each center, the clinician and the examiner were the same person. The centers were connected with a monitoring facility at the Department of Periodontology, Göteborg University. The study protocol was approved by the regional human review board.

An investigators meeting was arranged prior to the start of patient recruitment. Following a screening examination, subjects who met the inclusion criteria (see below) were following informed consent entered into the study, registered and randomly assigned (central monitor unit) to treatment group.

Subject sample

Inclusion/exclusion criteria

A subject to be included in the study must

- be between 25 and 75 years of age,
- be in good general health,

- not be on any medication or use any drug that, according to the responsible clinician, could jeopardize treatment outcome,
- not exhibit signs of untreated periodontitis or other mucosal and bone tissue lesions,
- not be a heavy clencher or bruxer,
- be partially edentulous in the posterior segments of the maxilla or the mandible,
- have sufficient amount of bone ($\geqslant$9 mm) in the recipient sites to allow implant installation without the implementation of ridge augmentation procedures.

One-hundred partially edentulous subjects that (i) required at least one fixed partial denture (FPD) in the posterior segments of the dentition and (ii) met the inclusion criteria were initially recruited for the study.

According to the inclusion criteria, a given patient could contribute with more than one FPD (case). The screening examination, thus, revealed that this subject sample would provide in all 136 FPDs (cases). Each eligible patient received on an individual basis a detailed case presentation that described the condition of their dentition. Information was provided regarding the objective and the design of the study. All subjects signed informed consent forms.

Prior to the pre-surgical (clinical/radiographical) examination, 16 patients reported that they preferred treatment that included either removable partial dentures or tooth-supported FPDs. Thus, finally 84 patients (mean age 51.6 years), 48 females and 36 males entered in the prospective study (Table 1). In the final subject sample, there were 21 smokers and 63 non-smokers. They provided in all 115 FPDs (cases).

Each individual subject was assigned one patient and $\geqslant$one case numbers. This was managed through a central registrar at Göteborg University. For the randomization of cases, a custom-made program based on balanced random permuted blocks was utilized.

The *cases* (*FPDs*) were assigned to two different treatment groups:

(Group A) One-stage installation procedure, non-submerged technique; (Group B) two-stage installation procedure, submerged technique.

Several subjects contributed with cases to both groups A and B.

Pre-treatment

Periodontal, endodontal and open caries lesions were treated prior to implant installation. All patients, in addition, received careful oral hygiene instruction and training in self-performed plaque control measures.

Implant installation

The surgical treatment was performed under local anesthesia. One hour prior to surgery, the patient received 3 g of Amoxicillin® (Scand Pharm AB, Stockholm, Sweden). Six hours after the completion of implant installation another 1 g of Amoxicillin was provided.

The surgical technique used for fixture installation followed the outline described in the manual for the Astra Tech® Implant System.

During the surgical procedure, the *shape* (A–D) and *quality* (1–4) of the jawbone at the recipient site(s) were classified according to criteria proposed by Lekholm & Zarb (1985).

One-stage technique

In sites of group A, the fixtures were installed and immediately thereafter abutment (Uni® abutment; Astra Tech® System) connection was performed. The soft-tissue flaps were adjusted to the implants and sutured. The surgical wounds were closed with either interrupted or continuous sutures. The abutment portion of the implant was during healing exposed to the oral cavity. The sutures were removed after 1 week.

Two-stage technique

First procedure: In sites belonging to group B, the fixtures were installed and cover screws placed. The mucosal flaps were closed with sutures and the implants were during healing fully submerged. The surgical wounds were closed with either interrupted or continuous sutures. The sutures were removed after 1 week.

Second procedure: 3 months (mandible) or 6 months (maxilla) later, abutment (Uni® abutment; Astra Tech® System) connection was performed. The center of a submerged cover screw was identified with a probe and a *mucosal punch*® (Astra Tech® System) was used to remove the covering mucosa.

Following each surgical treatment, the patients received a chlorhexidine (0.15%; Ebur®, Milan, Italy) mouthwash and were told to rinse with the antiseptic solution twice a day for 10 days.

In both groups, the restorative treatment was initiated 3 months (mandible) and 6 months (maxilla) after implant installation. The restorative treatment steps followed recommendations provided in the manual for the Astra Tech® System. All FPDs were made of porcelain fused to gold and were retained with screws to the implants.

Examinations

Immediately following the installation of the FPD, a baseline examination was performed that included both clinical and radiographical measurements.

Plaque

At each site, the presence of plaque was scored on two surfaces buccal and lingual/palatal) of the implant. The mean percentage of plaque harboring surfaces was calculated using the case (FPD) as the unit.

Table 1. Some overall characteristics of the sample

number of subjects	84	36 men, 48 women
		63 non-smokers, 21 smokers
mean age		51.6 years
number of implants installed	324	145 maxilla, 179 mandibles
number of FPDs (cases)	115	50 maxilla, 65 mandible
number of FPDs per patient	1	56 patients
	2	26
	3	1
	4	1
number of implants per FPD	2 implants	28 FPDs
	3	83
	4	4

FPD, fixed partial denture.

Soft-tissue inflammation

The presence of soft-tissue inflammation (redness and/or bleeding) was assessed on buccal and lingual/palatal aspects of each implant. The mean percentage of inflamed sites was calculated using the case as the unit.

Bone level

A custom-made film holder was produced for each patient and FPD site. In the radiographs, the distance between the fixture head and the apical level of the marginal bone that was in contact with the implant was determined by the use of a magnifying lens ($\times 7$) to the nearest 0.1 mm. The measurements were made at the mesial and distal aspects of each fixture and the mean value for the case calculated. The radiographic examination was performed at the Department of Oral and Maxillofacial Radiology, at The Sahlgrenska Academy at Göteborg University and by experienced radiologists who were otherwise not involved in the study.

Clinical and radiographical examinations were repeated once a year after the baseline examination.

Data analysis

The primary outcome variable was the change in the bone level at the implants from the time of placement of the bridge (FPD) to the 1- and 2-year reexaminations. In the comparison between groups A and B, a given subject/patient treated with >1 FPD could contribute to any of the two groups with more than one case. In such a situation, the mean bone-level change for the patient and group was calculated.

For description of the data, mean values and standard deviations were calculated.

Fisher's permutation test (Bradley 1968) was used to test if differences existed between groups A and B, and between patients (men/women, smokers/non-smokers, age), sites (maxilla/mandible) and implants (length, diameter). Pitman's test (Bradley 1968) was used to study correlations between bone shape and quality data and different radiographic bone-level data. Both tests are non-parameteric and $p<0.05$ was considered to be significant.

Results

Table 1 presents some overall characteristics of the subject sample. Of the 84 patients that entered into the study, 48 were women and 36 were men. Their mean age was 51.6 years; 63 were non-smokers and 21 smokers. Three hundred and twenty-four implants were placed, 145 in the maxilla and 179 in the mandible. One hundred and fifteen screw-retained FPDs (cases) were inserted, 50 in the maxilla and 65 in the mandible. Fifty-six patients contributed with one FPD, 26 patients with two FPDs, one patient with three and one patient with four FPDs. Further, 28 FPDs were supported by two implants, 83 FPDs with three implants and four FPDs by four implants.

Table 2. Characteristics of the implant supported fixed partial dentures (FPDs or cases) that was placed in groups A and B

	Group A	Group B
Number of FPDs	55	60
Jaw (maxilla/mandible)	23/32	27/33
Number of implants/FPD	2.8	2.9
Number of implants 3.5/4.0	106/47	114/57
Mean length of implants (mm)	11.8	11.7
Frequency of		
8–9 mm	46	52
11–13 mm	76	84
$\geqslant$15 mm	31	35
Number of implants in position		
14, 15, 24, 25	41	48 = 89
34, 35, 44, 45	33	43 = 76
16, 17, 26, 27	19	23 = 42
36, 37, 46, 47	55	46 = 101

Table 2 describes some additional characteristics of groups A (one-stage protocol) and B (two-stage protocol). The number of FPDs in groups A and B were 55 and 60, respectively. In group A, there were 23 FPDs in the maxilla and 32 in the mandible. The corresponding numbers for group B were 27 and 33. The mean number of implants per FPD was 2.8 in group A and 2.9 in group B.

In both groups, the majority of the implants used had a diameter of 3.5 mm; group A: 106 out of 153, group B: 114 out of 171.

Ninety-eight of the implants placed were 8–9 mm long (46 in group A and 52 in group B), 160 were 11–13 mm long (76 in group A and 84 in group B) and 66 implants (31 in group A and 35 in group B) were $\geqslant$15 mm in length.

Three hundred and eight of the 324 implants used in the current study were placed in positions distal of the canine tooth regions. In the pre-molar region, there were 89 implants (41 in group A and 48 in group B) in the maxilla and 76 (33 in group A and 43 in group B) in the mandible. In the molar regions, there were 42 implants installed in the maxilla (19 and 23 in groups A and B) and 101 (55 in group A and 46 in group B) in the mandible.

Following placement, 14 fixtures in group A and 10 fixtures in group B were by the surgeons scored as having reduced ''initial stability''.

Failures and dropouts

Seven implants (four in group A and three in group B) failed to integrate during the process of healing. Five of the seven early failures (three in group A and two in group B) were found among the 24 fixtures that following insertion exhibited a reduced ''initial stability''.

All seven failures were identified prior to FPD placement and removed. At four sites with such early failures, new implants were installed and FPDs placed according to protocol.

Table 3 describes the number of implants (and FPDs) present at the time of bridge insertion (baseline) and at the two annual follow-up examinations. During the first year of function, one FPD, supported by two implants, was lost to follow-up in group B. During the second 12-month interval, three FPDs (nine implants) were lost to follow-up in group B and one FPD with three implants in group A.

Thus, 14 implants were lost to follow-up during the 2 years of monitoring; three in group A and 11 in group B and. In group A, all three implants that could not be accounted for occurred in the maxilla. In group B, three of the

unaccounted implants had been placed in the maxilla and eight in the mandible.

Radiographic bone-level change

Overall

The mean overall radiographic bone level was at baseline located a distance of 1.46 ± 0.92 mm apical of a fixed reference level in the marginal portion of the fixture part of the implants. During the course of the first 24 months following the installation of the FPDs there was a small amount of bone support that was lost (Table 4). This reduction of the periimplant bone level amounted to 0.08 ± 0.47 mm during year 1 and 0.06 ± 0.57 mm in the interval between baseline and the 2-year follow-up examination. In the interval between 12 and 24 months, there was a small gain of bone.

The bar charts in Fig. 1 illustrate the frequency of FPDs (cases) that exhibited varying amounts of bone loss during (i) year one (Fig. 1a) and (ii) years 1 and 2 (Fig. 1b) of function. In the first interval (year 1) the majority of the FPDs exhibited bone-level alteration within the +0.3 mm and −0.3 mm range. The group of implants that supported two of the FPDs had gained on the average 1.2 and 1.1 mm bone, respectively, while the group of implants in another three of the FPDs had suffered on the average 1.7, 1.9 and 2.0 mm bone loss. In the interval between baseline and 24 months (i) the majority of the FPDs ($n = 78$) had experienced bone-level alterations between +0.4 mm (six cases) and −0.5 mm (five cases). It was further observed that five FPDs appeared to have improved the periimplant bone level with $\geqslant 0.6$ mm while three FPDs had lost $\geqslant 1.8$ mm. Fig. 2 presents the frequency of implants that gained or lost implants during the first and second years of function. While the majority of implant sites appeared to gain some bone during this interval seven sites (2.1%) exhibited a reduction of the bone level that amounted to >1.5 mm.

Table 3. Reason for loss of implants (FPDs) at follow-up examinations

	Number of implants		
		Failure	Lost to follow-up
At implant placement	324		
At FPD placement	321	7 (−4 = 3)	
At follow-up	Total (A/B)		
1 year	319 (167/152)		2
	307 (158/149)		12

		Number of FPDs	
		Group A	Group B
At FPD placement	total	55	60
	maxilla	23	27
	mandible	32	33
At follow-up			
1 year	total	55	59
	maxilla	23	27
	mandible	32	32 (−1)
2 years	total	54	56
	maxilla	22 (−1)	26 (−1)
	mandible	32	30 (−2)

FPD, fixed partial denture.

Table 4. Periimplant bone-level change (mm) that occurred between baseline (BL) and 12 months and between BL and the 24-month reexamination

	BL–12 months	BL–24 months	*p*-value
Overall	0.08 ± 0.47	0.06 ± 0.57	
Gender (men/women)	$0.06 \pm 0.42/0.18 \pm 0.52$	$0.04 \pm 0.52/0.22 \pm 0.62$	0.30, 0.16
Maxilla/mandible	$0.17 \pm 0.61/0.06 \pm 0.034$	$0.11 \pm 0.67/0.11 \pm 0.53$	>0.30, >0.30
Non-smokers/smokers	$0.18 \pm 0.51/+\mathbf{0.04 \pm 0.28}$	$0.22 \pm 0.62/+\mathbf{0.09 \pm 0.42}$	0.046, 0.036
Age			
<40	0.48 ± 0.80	0.61 ± 0.87	
40–60	0.11 ± 0.40	0.10 ± 0.52	
>60	$+\mathbf{0.04 \pm 0.42}$	$+\mathbf{0.03 \pm 0.52}$	0.010
Implant diameter			
3.5 mm	0.17 ± 0.5	0.19 ± 0.6	
4.0 mm	0.05 ± 0.4	$+\mathbf{0.05 \pm 0.6}$	0.07
Bone shape (A, B, C, D)			
A	0.08 ± 0.21	0.11 ± 0.5	
B	0.11 ± 0.44	0.08 ± 0.6	
C	0.15 ± 0.62	0.17 ± 0.71	
D	0.12 ± 0.19	0.17 ± 0.15	>0.30
Bone quality			
1	$+\mathbf{0.02 \pm 0.09}$	0.04 ± 0.19	
2	0.14 ± 0.71	0.14 ± 0.76	
3	0.11 ± 0.44	0.02 ± 0.58	
4	0.34 ± 0.35	0.53 ± 0.38	>0.30

Numbers presented in **bold** indicate that *a gain* of the periimplant bone level had occurred.

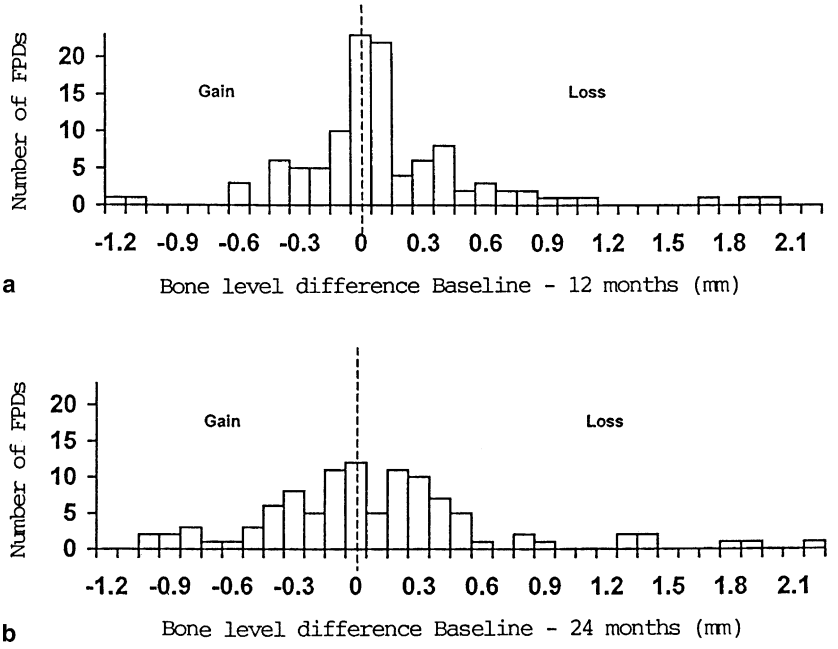

Fig. 1. Bar chart that describes the frequency of fixed partial dentures (FPDs) that, during the first (baseline – 12 months; a) and second (baseline – 24 months; b) examination intervals, lost or gained periimplant bone. Only three cases exhibited a periimplant bone-level change that was >1.5 mm.

The amount of bone-level reduction (Table 4) appeared to be larger in women than in men (0.22 versus 0.04; $p>0.05$), and more pronounced in younger (<40 years) than in older (>60 years) subjects. The analysis revealed that in this sample there was a significant correlation between age and bone-level change.

In the first examination interval, i.e. baseline to 12 months there was three times as much periimplant bone loss at implants in the maxilla as in the mandible (0.17 mm versus 0.06 mm; $p>0.05$). This difference was not observed when the baseline–24-month alterations was considered.

Implants with the larger diameter (4.0 mm) experienced during the 24-month interval some periimplant bone-level gain (+0.05 mm) while implants with the smaller diameter (3.5 mm) had experienced some loss (0.19 mm; $p<0.05$; Table 4).

The amount of periimplant bone loss that occurred at implants of varying length was also determined. Pitman's test demonstrated that there was no correlation ($p>0.30$) between fixture length (8 mm–19 mm), the bone level at baseline and bone-level change over time, i.e. baseline – 12 months and baseline – 24 months.

Bone-level alterations at implants placed in differently *shaped* recipient sites with different *quality* of the bone tissue (Lekholm & Zarb 1985) were assessed for different FPDs (Table 4). In both the first and second examination intervals, FPDs placed in *quality* 4 bone appeared to have lost more marginal bone than FPDs retained in sites that scored quality 1, 2 or 3. Pitman's test disclosed that there was no overall correlation ($p>0.30$) between bone *quality* and bone-level change over time. A further analysis revealed, however, that the bone-level change in both the first and the second examination intervals was significantly larger ($p<0.05$; Fisher's permutation test) than at implants placed in *quality* 4 bone than at sites with dense bone (*quality* 1).

Groups A and B (Table 5): Both in groups A and B, the implants supporting the FPDs experienced some periimplant bone loss during the 2 years of monitoring. In both groups, this bone-level change occurred during the first 12 months of function; 0.02 mm in group A and 0.17 mm in group B. The large standard deviations (0.38 and 0.51 mm) indicated that the bone-level change varied considerably between cases in both groups A and B. The difference between the groups with respect to bone-level change in the two examination intervals was not statistically significant. The bar chart in Fig. 3 describes the frequency of FPDs that exhibited varying degree of bone gain and loss during the first (Fig. 3a) and second (Fig. 3b) examination intervals. In the first interval, the majority of the FPDs exhibited a bone-level change that varied between +0.2 and −0.3 mm. Three FPDs, two from group B and one from group A had experienced >1.5 mm bone loss. In the second interval, the majority of FPDs exhibited a bone-level change that varied between +0.6 an –0.5 mm with six FPDs (four from group B and two from group A) exhibiting a bone loss of >1.2 mm. Three FPDs (two from group A and one from group B) exhibited a bone-level reduction of $\geqslant$1.7 mm.

Table 6 portrays the outcome of treatment in groups A and B for FPDs placed in the maxilla and in the mandible. The mean values describing bone-level change indicated that only small amounts of bone loss occurred at implants in the two jaws during the 2 years of monitoring. Thus, the differences between the bone levels recorded at baseline and 24 months in the two groups amounted to 0.06 and 0.15 mm (maxilla) and 0.01 and 0.22 (mandible).

A further analysis included FPDs that exclusively were supported by implants placed in the posterior part of the dentition, distal of the canine position (Table 6). In both groups, the bone-level change for FPDs placed in the posterior maxilla and posterior mandible was similar.

FPDs in group A exhibited less reduction of the periimplant bone level in both the first and second examination intervals than corresponding FPDs in group B. Between baseline and 2 years, FPDs in the maxilla gained 0.02 ± 0.44 mm bone, while FPDs in the same location in group B lost 0.20 ± 0.78 mm.

Oral hygiene and soft-tissue inflammation

During the pre-treatment phase, all subjects included in the study had adopted proper oral hygiene habits. This is illustrated by the fact that the plaque and inflammation scores obtained at baseline were low, 6.6% and 3.0%, respectively (Table 7). At the reexaminations after 1 and 2 years, the score values in both groups had increased to levels of about 12% (*plaque*) and 6% (*soft-tissue inflammation*).

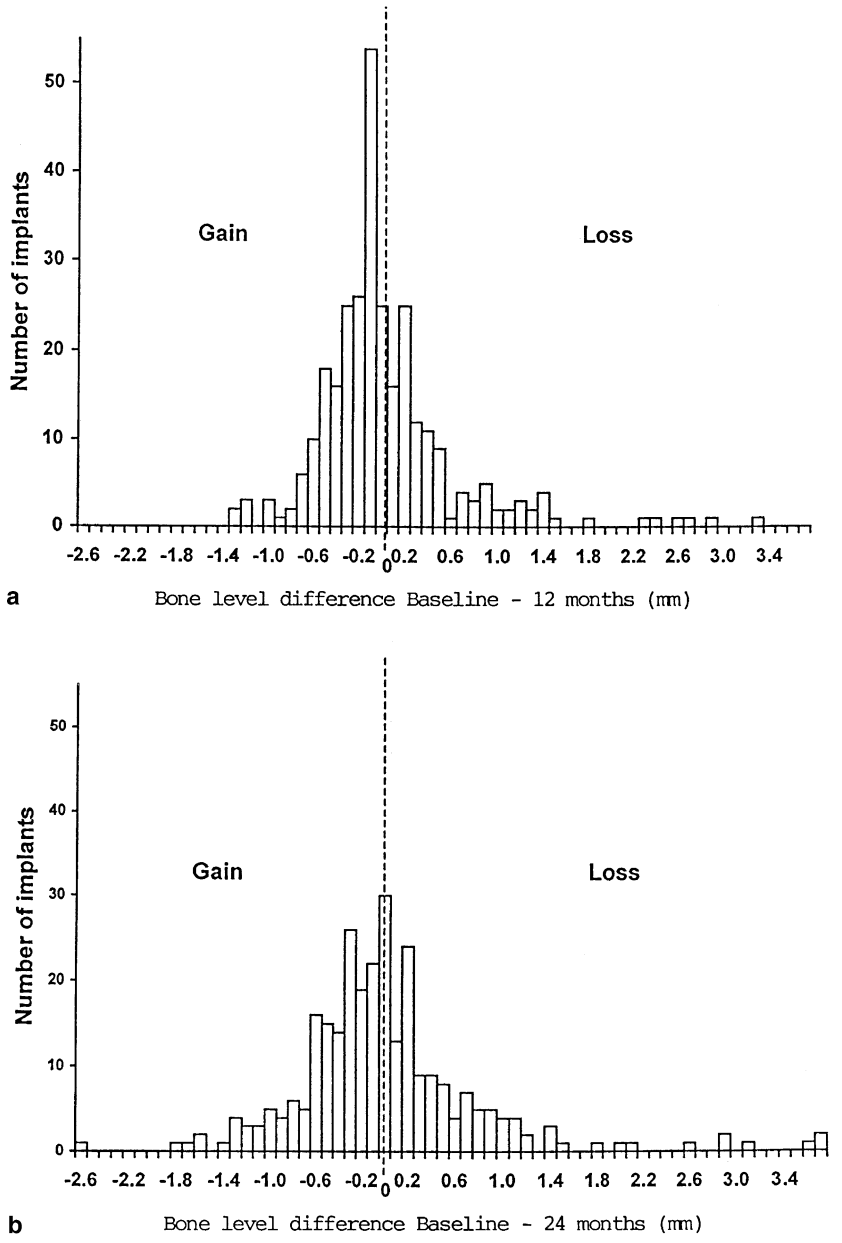

Fig. 2. Bar chart that portrays the number of implants that exhibited gain or loss of periimplant bone height during baseline – 12 months (a) and baseline – 24 months (b). Seven implants exhibited a bone loss of >1.5 mm while seven implants gained >1 mm of bone.

Table 5. Periimplant bone-level change (mm) that occurred in groups A and B between baseline (BL) and 12 months and between BL and the 24-month reexamination

Treatment	Group A	Group B	*p*-value
BL–12 months	0.02 ± 0.38	0.17 ± 0.51	0.11
12–24 months	0.00 ± 0.28	0.00 ± 0.29	0.23

Discussion

The findings of the present randomized controlled clinical trial demonstrated that tissue healing following implant installation appeared to be independent of the surgical protocol, i.e. whether the marginal portions of the implants during surgery were fully or only partly submerged under the ridge mucosa. Thus, in both treatment groups the number of implants that failed to osseointegrate (early failures) was small ($<2\%$). Further, at the end of the recommended periods of bone healing prior to loading – maxilla 6 months and mandible 3 months – in both groups, the level of the marginal bone was close to the coronal rim of the fixture.

The current study also demonstrated that, irrespective of surgical installation protocol (two-stage, one-stage) implants supporting the FPDs exhibited only small amount of radiographic bone loss during the first year of function (group A: 0.02 ± 038 mm; group B: 0.17 ± 0.64 mm). Moreover, during the second year of function, the amount of additional bone loss that occurred in the two treatment groups was close to zero.

Based on the above findings there are reasons to suggest that it may be not necessary to submerge implants of the Astra Tech® System during the initial phase of healing in order to obtain proper soft- and hard-tissue modeling and osseointegration.

Seven implants (2.1%), four in the maxilla and three in the mandible, failed to osseointegrate during the process of healing. Four of the early failures occurred in group A and three in group B. This low frequency of early failures agrees with findings from previous studies using different implant systems in fully and partially edentulous patients (e.g. Adell et al. 1990a, b, Friberg et al. 1991, Becker et al. 1997, Karlsson et al. 1998, van Steenberghe et al. 2000, Engquist et al. 2002; for review see Esposito 1999, Berglundh et al. 2002).

The most important observation made in the present study was that periimplant bone-level change did not differ between groups A and B during years 1 and 2 of function. This finding is in agreement with data previously reported from animal experiments (e.g. Gotfredsen et al. 1991, Abrahamsson et al. 1996, 1999, Ericsson et al. 1996, Weber et al. 1996) in which only minor, if any, differences were noted concerning amount and quality of soft and hard tissues formed around the titanium rods during healing between implants placed according to submerged and non-submerged treatment protocols. The current results are also in agreement with data from prospective studies and case reports in humans (e.g. Ericsson et al. 1994, 1997, Henry & Rosenberg 1994, Bernard et al. 1995, Balshi & Wolfinger 1997, Becker et al. 1997, 2000, Schnitman

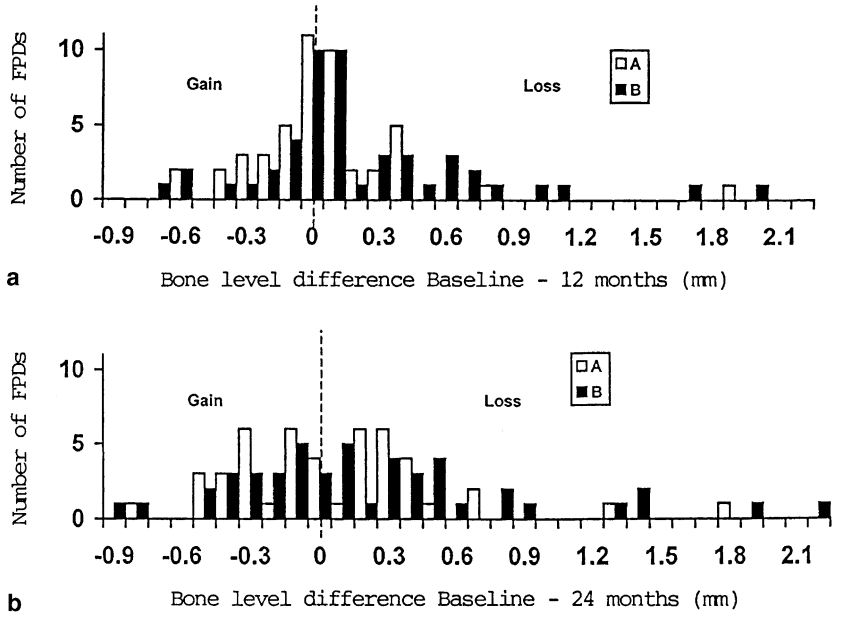

Fig. 3. Bar charts that describe the number of fixed partial dentures (FPDs) in groups A and B that presented with varying amounts of periimplant bone loss during the first 12 months (a) and in the interval between baseline and 24 months (b). Only three FPDs – one in group A and two in group B exhibited a bone-level reduction that was >1.5 mm.

Table 6. Periimplant bone-level change (mm) that occurred at implants supporting FPDs in the maxilla and in the mandible of groups A and B between baseline (BL) and the reexaminations

	Maxilla		*p*-value	Mandible		*p*-value
	Group A	Group B		Group A	Group B	
Overall						
BL–12 months	0.13 ± 0.52	0.20 ± 0.69	>0.30	$+\mathbf{0.03 \pm 0.25}$	0.17 ± 0.40	0.04
BL–24 months	0.06 ± 0.58	0.15 ± 0.74	>0.30	0.01 ± 0.45	0.22 ± 0.59	0.18

Numbers presented in **bold** indicate that *a gain* of the periimplant bone level had occurred.

Table 7. Frequency distribution of plaque and inflammation scores obtained from the examinations at baseline and after 1 and 2 years of monitoring

	Total	Group A	Group B	*p*-value
Plaque (%)				
baseline	6.6 ± 18.8	4.7 ± 14.5	8.4 ± 22.3	>0.30
1 year	11.5 ± 25.5	7.8 ± 18.9	15.1 ± 30.3	0.18
2 years	12.7 ± 23.5	11.3 ± 21.9	14.0 ± 25.0	>0.30
Inflammation (%)				
baseline	3.0 ± 9.2	2.4 ± 9.1	3.5 ± 9.3	>0.30
1 year 11.6	4.8 ± 11.1	2.9 ± 8.0	6.7 ± 13.2	0.12
2 years 11.9	6.5 ± 17.8	3.0 ± 8.0	9.9 ± 23.4	0.067

et al. 1997, Tarnow et al. 1997, Randow et al. 1999) that demonstrated that the marginal bone level following rehabilitation appeared to remain stable irrespective of whether the implants had been placed according to a one- or two-step surgical protocol.

Albrektsson & Isidor (1993) in a consensus report modified the originally proposed criteria of success for dental implant systems (Albrektsson et al. 1986) and stated that pronounced, progressive reduction of the periimplant bone level is a sign of failure of implant therapy. They suggested that criteria for success should demand ''an average marginal bone loss of less than 1.5 mm during the first year'' and thereafter <0.2 mm annual bone loss. In this context, it should be realized that in the current sample the average periimplant bone loss during the first year following the insertion of the FPDs was only 0.08 ± 0.47 mm. The corresponding periimplant bone-level change during year 2 was close to zero. In other words, the implant system used in the present multicenter study met the proposed criteria of success. The finding that only minor amounts of progressive periimplant bone loss took place during function (loading) in patients restored with implants of the Astra Tech® System is in agreement with data reported in previous clinical studies including fully and partially edentulous jaws and patients (e.g. Makkonen et al. 1997, Karlsson et al. 1998, van Steenberghe et al. 2000, Steveling et al. 2001, Yi et al. 2001, Engquist et al. 2002).

Albrektsson & Isidor (1993) also recommended that the frequency distribution of data should be ''added to the reporting''. Such frequency distributions describing the cases and implants in the current subject sample are presented in Figs. 1 and 2. It is obvious from the data reported in the bar charts that only three cases out of 115 (2.6%) and seven implants out of 321 (2.2%) exhibited bone loss during years 1 and 2 that exceeded the values included in the recommended criteria.

In the present study, it was observed that implants that were placed in *quality 4 bone* (Lekholm & Zarb 1985) during the first year of function exhibited a periimplant bone loss that amounted to 0.34 ± 0.35 mm while implants placed in *quality 1 bone* in the same interval *gained* on the average 0.02 ± 0.09 mm bone (<0.05). This observation is in agreement with, e.g. Friberg et al. (1991), Jemt (1993), Sullivan et al. (1997), who found higher failure rates for implants placed in trabecular bone than in sites with hard tissue with larger amounts of cortical bone. On the other hand, it should be recognized that other authors have failed to confirm that quality 4 bone provided poor healing conditions following implant installation (Bahat 1993, Truhlar et al. 1997).

It has been claimed that in the fully edentulous patient restored with implant wearing fixed prostheses or overdentures, progressive periimplant bone-level reduction as well as implant loss during function was more frequent in the maxilla than in the mandible, while

this difference between jaws appeared not to be valid for implants and FPDs placed in partially dentate subjects (for review see Esposito 1999). The findings from the present follow-up examinations confirmed previous findings. Thus, in group A as well as in group B, the amount of periimplant bone-level change that occurred between baseline and year 1(2) in the maxilla as well as in the mandible was small and the difference between jaws not statistically significant.

The observation that the surgical protocol does not influence the outcome of implant therapy i.a. apparently not only to be valid for FPD restorations but also for single-tooth replacements. Thus, Ericsson et al. (2000) studied the result of single-tooth replacements in the maxillary front tooth regions of implants installed according to a one-stage surgical procedure in comparison with ''the original two-stage concept'' for implants of the Brånemark® System. The authors reported that the periimplant bone-level change during the first year of function at implants was small and varied between +0.08 mm (loss) for the one-stage and −0.05 (gain) for the two-stage protocol.

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